Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

Protocol summary

Study aim
Comparison of the effectiveness of leg ergometry exercises with and without WB-EMS on blood glucose regulation in patients with type II diabetes in Imam Khomeini Hospital, Sari, in 2023

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 patients. SNOSE will be used for randomization.

Settings and conduct
Imam Khomeini Hospital, Sari, patients with type II diabetes will be included in the study according to the entry and exit criteria. In the clinical trial study, the SNOSE method will be used to hide (blinding) the random allocation.

Participants/Inclusion and exclusion criteria
Entry conditions: patients with type II diabetes, age 30 to 70 years, consent to participate in the study, 7<HbA1C<10, no exogenous insulin use, BMI>25, no heart pacemaker and defibrillator, no heart failure
Symptomatic and uncontrolled exclusion conditions: lack of consent to participate in the study, withdrawal from participation in the study, absence of more than 2 sessions, presence of new diabetic foot ulcers or musculoskeletal defects, pregnant women, breastfeeding, presence of serious orthopedic, neurological or infectious disorders (joint Charcot, diabetic foot ulcer, amputation), uncontrolled seizures

Intervention groups
1) Patients receiving aerobic exercise by Leg Ergometry along with EMS 2) Patients receiving aerobic exercise by Leg Ergometry method without receiving EMS. The exercise that each patient receives is Leg Ergometry or stationary bicycle, which is performed for 30 minutes in the group without EMS and 20 minutes in the group with EMS. 3 sessions per week for 8 weeks of this training protocol will be done

Main outcome variables
Blood sugar level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210901052353N1**
Registration date: **2024-03-02, 1402/12/12**
Registration timing: **prospective**

Last update: **2024-03-02, 1402/12/12**
Update count: **0**

Registration date
2024-03-02, 1402/12/12

Registrant information

Name
seyed ali akbar mahmoudi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4440 5204

Email address
amahmoudi@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-09, 1402/12/19

Expected recruitment end date
2024-04-19, 1403/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

Public title

Comparing the effectiveness of Leg Ergometry exercises with and without WB-EMS on blood sugar regulation in patients with type II diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type II diabetes Age 30 to 70 years Consent to participate in the study HbA1C<10>7 No use of exogenous insulin BMI>25 Absence of pacemaker and defibrillator Not having symptomatic and uncontrolled heart failure Absence of psychiatric disorders No history of CVA, MI, Unstable angina in the last month Not having uncontrolled HTN

Exclusion criteria:

Lack of consent to participate in the study Withdrawal from participating in the study Absence of more than 2 sessions Presence of new diabetic foot ulcer or musculoskeletal defects pregnant lady breastfeeding Presence of serious orthopedic, neurological or infectious disorders (Charcot's joint, diabetic foot ulcer, amputation) Uncontrolled seizures Severe proliferative and non-proliferative diabetic retinopathy Change in dosage and type of oral medication

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation by the method of variable blocks. In this study, the randomization method will be used to generate a random sequence using the block method and the Random allocation software. First, the informed consent form is registered by the patient in writing, and then the participants will be randomly assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

SNOSE method will be used to hide random allocation. This method is one of the common methods in hiding random allocation. In this method, a random sequence is first created using the mentioned software, then based on the sample size of a number of envelopes with aluminum wrappers (in order to make the contents of the envelopes unclear), prepare and each of the random sequences created on It is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of the registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences, Imam Khomeini Hospital, Sari

Street address

Amir Mazandarani Boulevard, Imam Khomeini Hospital

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2023-12-17, 1402/09/26

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1402.105

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood sugar decreasing

Timepoint

At the beginning and before entering the study and at the end of week 8

Method of measurement

blood test

Secondary outcomes

1

Description

Oxygen consumption capacity or aerobic capacity per person

Timepoint

At the beginning and before entering the study and at the end of week 8

Method of measurement

Field test

Intervention groups

1

Description

Intervention group: Patients receiving aerobic exercise by Leg Ergometry along with EMS

Category

Treatment - Devices

2

Description

Control group: Patients receiving aerobic exercise by Leg Ergometry without receiving EMS

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Seyyed Ali Akbar Mahmoudi

Street address

Imam Khomeini Hospital, Amir Mazandarani Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

amahmoudi@mazums.ac.ir

Web page address

https://www.mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

Street address

Moalem Ave

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3325 7230

Email

m.saedi@mazums.ac.ir

Web page address

https://www.mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyed Ali Akbar Mohammadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

Amir Mazandarani Boulevard, Imam Khomeini Hospital

City

Sari

Province
Mazandaran
Postal code
48166-33131
Phone
001133361700
Fax
Email
amahmoudi@mazums.ac.ir
Web page address
https://www.mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Seyed Ali Akbar Mohammadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Amir Mazandarani Boulevard, Imam Khomeini Hospital
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
001133361700
Email
amahmoudi@mazums.ac.ir
Web page address
https://www.mazums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Seyed Ali Akbar Mohammadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Amir Mazandarani Boulevard, Imam Khomeini Hospital
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
001133361700
Email
amahmoudi@mazums.ac.ir
Web page address
https://www.mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available